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for

METHODS AND APPARATUSES FOR NAVIGATING THE SUBARACNHNOID SPACE

by

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BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to surgical methods and medical devices. More particularly, it concerns methods and apparatuses useful in navigating the subarachnoid space, including the spinal and the intracranial subarachnoid spaces. It also concerns medical devices, such as sheaths, that are suited for attachment to the skin.

2. Description of Related Art

During the 20th century, brain neurosurgery has advanced via the introduction of microsurgical techniques, the development of new tools such as aneurysm clips, and the description of new operative approaches. Surgeons have developed elegant mechanisms to remove parts of the bones making up the skull (craniotomy) and operate on structures deep within the brain while attempting to minimize complications relating to the approach. [See, for example, Fries et. al., 1996.] Furthermore, the surgical approach to the intracranial and spinal subarachnoid space has historically consisted of the skin incision, dissection to either the cranium or spinal bony covering, removal of some bone, and dissection through the meninges to gain access to the neurological structures. While imaging modalities became integrated into diagnostic evaluations, only at the end of the last century were significant attempts made to integrate computed tomography, angiography, and most recently magnetic resonance (MR) scanning into the actual surgical procedures.

Unfortunately, craniotomy has limited the applicability of such imaging modalities because the surgeon cannot simultaneously stand at the patient's head and conveniently operate on the brain via craniotomy, maintain sterility, and scan the brain using a large scanning apparatus that requires the patient to be held within it. There are theoretical limits to the ability to conveniently perform such surgery using currently-available imaging devices due to a conflict between the means of acquiring images and the means of operating on the brain. Furthermore, in conventional neurosurgery, while the brain surface is readily available underlying a craniotomy, the approach to deeper structures is progressively more invasive in terms of retraction injury (i.e., the brain is

often retracted after the craniotomy to facilitate access to different areas in and around the brain) or even the need to remove brain tissue to gain access.

During the last 20 years, the development of endovascular neurosurgery has resulted in the creation of specialized devices for application within arteries. These devices include not only catheters and guidewires, but also embolic materials that can be introduced via catheters, thereby enabling the enhancement of some procedures that are performed via craniotomy following embolization, and thereby eliminating the need for craniotomy altogether in other cases. However, these techniques have heretofore been limited to the intravascular space (i.e., the space within blood vessels) because that was seen as the only available route of access for catheterization of the intracranial contents.

Extravascular access to locations within the head for the purpose of facilitating the kinds of procedures heretofore performed following a craniotomy has not been reported to the inventor's knowledge. The subarachnoid space, which is a compartment that contains the body of the spinal cord and cerebrospinal fluid (CSF)—a fluid that fills and surrounds the ventricles (cavities) of the brain and the spinal cord, and acts as a lubricant and a mechanical barrier against shock—is one such extravascular route.

Some authors have described experimental data using endoscopy in the subarachnoid space. An endoscope is a tube with a light and a lens on the end that can be used to view various regions within a body. One group from Sweden utilized a relatively large (4 millimeter) bronchoscope (a type of endoscope) to travel the length of the subarachnoid space to eventually visualize the contents of the posterior fossa, as well as gain access to the ventricular system. [Stefanov et. al., 1996.] These studies were performed in cadavers and involved dissection to the lumbar space and introduction of the bronchoscope from that location, using only endoscopic guidance. Applications in the clinical setting were not advocated.

A group from Japan utilized a smaller endoscope in cadavers to access only the subarachnoid space around the spinal cord and posterior fossa. [Eguchi et. al., 1999.] No attempt was made to access either the ventricles or the supratentorial cisterns. The endoscopes used also had no directional capability. Uchiyama et. al. (1998) used a "myeloscope" (a type of endoscope) that was sufficiently small (0.5-2 mm) to safely

access the spinal subarachnoid space without injuring the spinal cord in a group of patients. Neither of these articles discusses catheterizing the subarachnoid space, whether for the purpose of facilitating intracranial access or otherwise. Furthermore, neither group attempted navigation of the subarachnoid space using catheters and guidewires or other means to more precisely control device placement or other instrument insertion.

Amar et. al. (2001) recently described a technique of catheterizing the spinal epidural space for the introduction of medication. However, that technique did not involve catheterization of the subarachnoid space, nor was it performed for the purpose of facilitating intracranial access. Other techniques of delivering anesthetics and other therapeutic agents to the subarachnoid space using catheters are described in U.S. Patent Nos. 5,085,631 and 5,470,318.

The techniques disclosed in these patents do not involve advancing the catheter toward the head of the patient after the catheter is introduced into the subarachnoid space. Nor do they involve steps that facilitate intracranial access. Neither patent discloses using catheters for introducing other medical devices through the passageways in those catheters for the purpose of facilitating intracranial access.

The inventor is aware of other techniques for delivering medicaments to the subarachnoid space using a catheter. However, of these, none involved the use of catheters for the purpose of facilitating intracranial access. [See, for example, Delhaas, 1996.]

In addition, medical devices (e.g., sheaths) that are used with the foregoing techniques to facilitate the introduction of endoscopes and catheters into the subarachnoid space are not well-suited for use with imaging modalities such as MR scanning. Generally, once a sheath is in place within a patient, other devices such as endoscopes and catheters can be introduced into the patient through the passageway within the sheath. In other words, once the sheath is in place, one end of the sheath is located beneath the patient's skin while the other end sticks out of the patient's skin, thereby allowing the surgeon to introduce, for example, an endoscope or catheter into the patient through the sheath's passageway. The manipulations that cause these introductions to

occur are carried out at the end of the sheath that is positioned outside of the patient. However, a traditional sheath is sized and configured such that it does not extend very far outside of a patient once it has been inserted into a desired location. As a result, the manipulations of other medical devices introduced through the sheath cannot feasibly take place while the patient is positioned within an MR scanner (which mainly consists of large magnets) because there simply is not enough of the sheath sticking out of the patient to work with. Furthermore, this same shortcoming would impede a surgeon's ability to use one or more robotic devices to assist in or completely perform these manipulations.

Based on the foregoing, new methods of facilitating intracranial access that do not involve the shortcomings of craniotomy, and that can be monitored or guided via various imaging modalities are needed. New methods of facilitating intracranial access via devices introduced through non-endoscopic devices are also needed. Furthermore, new medical devices useful for establishing access to areas such as the subarachnoid space, and that can be used with robotic instruments or while the patient is positioned within an MR scanner are needed.

SUMMARY OF THE INVENTION

The present invention addresses the shortcomings of the prior art by providing methods of navigating the subarachoid space that does not involve the removal of bone. In addition, the present invention provides a medical device that is suited for attachment to the skin, and which enhances the flexibility afforded to the operating carrying out the present methods.

In one respect, the invention is a method of navigating a spinal subarchnoid space in a living being. The method includes percutaneously introducing a device into the spinal subarachnoid space at an entry location. The device has a first passageway sized to slidably receive, and work with, at least a guidewire. The method also includes advancing the device within the spinal subarachnoid space at least more than 10 centimeters from the entry location.

In one embodiment, method also includes removing a portion of the brain of the living being. The living being contains cerebrospinal fluid, and in another embodiment, the method also includes flushing at least some cerebrospinal fluid in order to remove blood from that cerebrospinal fluid. In another embodiment, the method also includes inducing hypothermia in at least some brain tissue. In another embodiment, the method also includes accessing at least one ventricle located within the head with a second device introduced through the first passageway of the device. In another embodiment, the method also includes draining at least one ventricle located within the head after accessing the ventricle.

In another embodiment, the device includes a second passageway sized to slidably receive, and work with, at least a guidewire. In another embodiment, the method also includes introducing an endoscope through the first passageway of the device. In another embodiment, the device includes a first sub-elongated member that has the first passageway, and a second sub-elongated member coupled to the first sub-elongated member, and the second sub-elongated member has the second passageway. In another embodiment, the device also includes a braiding material wrapped around the first and second sub-elongated members.

In another embodiment, a cross section taken along the device has a shape that is non-circular. In another embodiment, the method also includes altering the temperature of at least some brain tissue using a pumping apparatus. In another embodiment, the method also includes delivering medication to an intracranial subarachnoid space. In another embodiment, the device includes a wall to which an electroencephalography electrode is attached. In another embodiment, the device includes a wall to which a sensor useful for monitoring a biochemical property is attached, and the method also includes monitoring either pH, glucose concentration, oxygen tension, carbon dioxide concentration, or sodium concentration using the sensor. In another embodiment, the device includes a wall to which a thermal sensor useful for monitoring temperature is attached, and the method also includes monitoring temperature using the thermal sensor.

In another embodiment, the method also includes introducing an apparatus through the first passageway of the device; and applying electric current, heat, or

cryothermal stimulation to a tissue within the living being using the apparatus. In another embodiment, the method also includes introducing a radioactive pellet through the first passageway of the device; and placing the radioactive pellet within the living being in order to irradiate a tumor. In another embodiment, the method also includes introducing a detector through the first passageway of the device; and placing the detector within the living being. In another embodiment, the method also includes monitoring a physiologic or biochemical property using the detector.

In another embodiment, the method also includes introducing a penetration apparatus through the first passageway of the device, the penetration apparatus including an outer sleeve element and an inner puncture element, the outer sleeve element and the inner puncture element being slidably coupled together; and puncturing the pia matter using the penetration apparatus. In another embodiment, the method also includes creating a lesion in the brain of the living being. In another embodiment, the advancing step of the method is achieved via a robotic device. In another embodiment, the method also includes monitoring the position of the device for a period of time using magnetic resonance imaging, fluoroscopy, endoscopy, computed tomography, thermal imaging, sonography, or any combination of these. In another embodiment, the method also includes introducing an electrode through the first passageway of the device; and placing the electrode within the living being. In another embodiment, the electrode is an electroencephalography electrode and the placing includes placing the electroencephalography electrode proximate brain tissue. In another embodiment, the method also includes introducing material through the first passageway of the device; and placing the material proximate a cranial nerve to assist in treating a neurologic condition. In another embodiment, the method also includes introducing genetic material through the first passageway of the device; and placing the genetic material within the living being to assist in treating a neurologic condition.

In another respect, the invention is a method of navigating a spinal subarchnoid space in a living being. The method includes percutaneously introducing a device into the spinal subarachnoid space. The device has a first passageway sized to slidably receive, and work with, at least a guidewire. The method also includes advancing the

device within the spinal subarachnoid space to facilitate intracranial access with a second device introduced through the first passageway.

In one embodiment, the method also includes removing a portion of the brain of the living being. The living being contains cerebrospinal fluid, and in another embodiment, the method also includes flushing at least some cerebrospinal fluid in order to remove blood from that cerebrospinal fluid. In another embodiment, the method also includes inducing hypothermia in at least some brain tissue. In another embodiment, the method also includes accessing at least one ventricle located within the head with a second device introduced through the first passageway of the device. In another embodiment, the device includes a second passageway sized to slidably receive, and work with, at least a guidewire. In another embodiment, the device includes a first sub-elongated member that has the first passageway, and a second sub-elongated member coupled to the first sub-elongated member, and the second sub-elongated member has the second passageway. In another embodiment, the device includes a wall to which a sensor useful for monitoring a biochemical property is attached, and the method also includes monitoring either pH, glucose concentration, oxygen tension, carbon dioxide concentration, or sodium concentration using the sensor.

In another embodiment, the method also includes introducing an apparatus through the first passageway of the device; and applying electric current, heat, or cryothermal stimulation to a tissue within the living being using the apparatus. In another embodiment, the method also includes introducing a radioactive pellet through the first passageway of the device; and placing the radioactive pellet within the living being in order to irradiate a tumor. In another embodiment, the method also includes introducing a detector through the first passageway of the device; and placing the detector within the living being. In another embodiment, the method also includes monitoring a physiologic or biochemical property using the detector. In another embodiment, the advancing step of the method is achieved via a robotic device. In another embodiment, the method also includes monitoring the position of the device for a period of time using magnetic resonance imaging, fluoroscopy, endoscopy, computed tomography, thermal imaging, sonography, or any combination of these.

In yet another embodiment, the method also includes introducing an electrode through the first passageway of the device; and placing the electrode within the living being. In another embodiment, the electrode is an electroencephalography electrode and the placing includes placing the electroencephalography electrode proximate brain tissue.

In another respect, the invention is a method of navigating a spinal subarachnoid space within a living being. The method includes introducing a non-endoscopic device into the spinal subarachnoid space. The non-endoscopic device has a passageway. The method also includes advancing the non-endoscopic device within the spinal subarachnoid space and toward the head of the living being to facilitate intracranial access with a second device introduced through the passageway; and monitoring the position of the non-endoscopic device for a period of time using an imaging modality other than an endoscope. In this document (including the claims), a "non-endoscopic device" is one that is not an endoscope. In this document (including the claims), an "endoscope" is a device to which a lens has been directly attached (usually at a tip of the device). A device such as one of the catheters or sheaths discussed below that has a passageway through which an endoscope is passed and with which an endoscope is used does not become an endoscope as a result.

In another respect, the invention is a medical device suited for attachment to a patient's skin. The medical device includes a member that has two ends and a first passageway sized to slidably receive, and work with, at least a guidewire; and a skin-attachment apparatus that is configured to be coupled to the member at a coupling location that is between the two ends. The skin-attachment apparatus has a flexible skin-attachment flap configured for attachment to the skin. The medical device also includes a valve apparatus that is configured to be coupled to one end of the member. The valve apparatus and the skin-attachment apparatus define a flexible member portion between them when both are coupled to the member.

In one embodiment, the coupling location is variable during a procedure. In one embodiment, the medical device also includes a second skin-attachment apparatus that is configured to be coupled to the member at a second coupling location that is spaced apart from the coupling location. In one embodiment, the flexible member portion has a length

of at least 2 centimeters. In one embodiment, a cross section taken along the member has a shape that is non-circular. In one embodiment, the member has a second passageway. In one embodiment, the member includes a first sub-elongated member that has the first passageway, and the medical device also includes a second sub-elongated member coupled to the first sub-elongated member, and the second sub-elongated member has the second passageway.

In another embodiment, the member is bendable, and is configured to retain a shape after being bent. In another embodiment, the valve apparatus is configured for use with a robotic device. In another embodiment, the member has a length, and a stiffness that varies along the length. In another embodiment, the two ends of the member are first and second ends; the valve apparatus is configured to be coupled to the first end; the member has a distal portion near the second end; and the distal portion includes a wall that has an electroencephalography electrode therein. In another embodiment, the two ends of the member are first and second ends; the valve apparatus is configured to be coupled to the first end; the member has a distal portion near the second end; and the distal portion includes a wall that has a sensor useful for monitoring a biochemical property. In another embodiment, the biochemical property is pH, glucose concentration, oxygen tension, carbon dioxide concentration, or sodium concentration. In another embodiment, the two ends of the member are first and second ends; the valve apparatus is configured to be coupled to the first end; the member has a distal portion near the second end; and the distal portion includes a wall that has a thermal sensor useful for monitoring temperature.

In yet another embodiment, the medical device also includes a flush line coupled to the valve apparatus. In another embodiment, the flexible skin-attachment flap includes padding material. In another embodiment, the valve apparatus includes a hub configured for attachment to other medical devices.

In another respect, the invention is a sheath suited for attachment to a patient's skin. The sheath includes a member that has a first end, a second end, and a first passageway sized to slidably receive, and work with, at least a guidewire. The sheath also has a skin-attachment apparatus that is configured to be coupled to the non-rigid

member at a coupling location that is between the first and second ends, but at least 2 centimeters from the first end. The skin-attachment apparatus has a flexible, padded skin-attachment flap configured for attachment to the skin. The medical device also includes a valve apparatus that is configured to be coupled to the first end of the member. The valve apparatus and the skin-attachment apparatus define a flexible member portion between them when both are coupled to the member. The coupling location may be varied either prior to or after attachment of the sheath to the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings form part of the present specification and are included to further demonstrate certain aspects of the present methods and apparatuses. The present methods and apparatuses may be better understood by reference to one or more of these drawings in combination with the description of illustrative embodiments presented herein. These drawings illustrate by way of example and not limitation, and they use like references to indicate similar elements.

FIG. 1 illustrates selected areas of the central nervous system and medical devices introduced into the spinal subarachnoid space using the present methods.

FIGS. 2A and **2B** are enlarged versions of the lumbar region of the spine shown in **FIG. 1**, and illustrate a medical device suited for attachment to the skin that was placed using the present methods.

FIG. 3 is a top view of a medical device suited for attachment to the skin and illustrated as a sheath.

FIGS. 4 – 9 illustrate different embodiments of the skin-attachment apparatus that is coupled to the sheath shown in **FIG. 3**.

FIG. 10 is a cross-sectional view of an embodiment of an elongated member of one of the present medical devices suited for attachment to the skin, illustrating a non-circular shape.

FIG. 11 is a cross-sectional view of an embodiment of an elongated member of one of the present medical devices suited for attachment to the skin, illustrating two passageways sized to slidably receive, and work with, at least a guidewire.

FIG. 12 is an end view showing two sub-elongated members coupled together.

FIG. 13A illustrates sub-elongated members of different lengths.

FIGS. 13B-H are partial side views illustrating different embodiments of ends of two coupled sub-elongated members.

FIG. 14 is a partial side view illustrating a detector attached to the outside surface of one of the present medical devices.

FIG. 15 is a cross-sectional view showing the detector depicted in **FIG. 14** being coupled to a communication device illustrated as a wire positioned in the wall of the medical device.

FIG. 16 illustrates an operator applying the present methods to a patient positioned within an MR scanner.

FIG. 17 illustrates a detector being placed in brain tissue using the present methods.

FIG. 18 depicts one embodiment of a penetration apparatus.

FIG. 19 is a partial side view depicting one embodiment of two sub-elongated members coupled together with a braiding material.

FIG. 20 is a partial side view depicting one embodiment of a catheter wrapped in braiding material.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

As a preliminary matter, it should be noted that in this document (including the claims), the terms "comprise" (and any form thereof, such as "comprises" and "comprising"), "have" (and any form thereof, such as "has" and "having"), and "include" (and any form thereof, such as "includes" and "including") are open-ended transitional terms. Thus, a thing that "comprises," "has," or "includes" one or more elements possesses those one or more elements, but is not limited to only possessing those one or more elements. For example, a device "having a first passageway sized to slidably receive, and work with, at least a guidewire" is a device that has, but is not limited to only having, the described first passageway. In other words, the device possesses the

first passageway, but is not excluded from possessing additional passageways or other elements that are not listed.

The present methods involve navigating the subarachnoid space, including the spinal subarachnoid space. In some embodiments, the intracranial subarachnoid space is also navigated. The present methods facilitate intracranial access via the subarachnoid space. For example, using the present methods, a first device may be introduced into the subarachnoid space to facilitate intracranial access with another device introduced through one or more passageways located within the first device. In this document (including the claims), "intracranial access" means access to the space within the head that is above the foramen magnum. In addition, intracranial subarachnoid space is the subarachnoid space located above the foramen magnum, and the spinal subarachnoid space is the subarachnoid space located below the foramen magnum, though the spaces are contiguous without a physical barrier between them. In this document (including the claims), a step that involves moving one device "to facilitate intracranial access" with another device introduced through the first device is a step that is taken with the intention of making intracranial access with the second device possible.

The present minimally-invasive methods offer new routes of access for both brain and spine surgery that involve no craniotomy or bone removal. Advantageously, the present methods can be performed with the operator standing remote from the patient's head. The route of access is a standard puncture of the spinal subarachnoid space, such as in the lumbar spine. Then, techniques conventionally used in intravascular procedures are applied in order to navigate the subarachnoid space, including the intracranial subarachnoid space in some cases. The present methods should have fewer problems with exposure of the brain to infectious agents and offer an opportunity for navigation of many structures without brain retraction or removal to achieve access.

Turning to the figures, **FIG. 1** illustrates certain aspects of the central nervous system of a patient that have been navigated using the present techniques. Specifically, **FIG. 1** illustrates dural membrane **10**, spinal cord **12**, subarachnoid space **14**, lumbar vertebrae **L1**, **L2**, **L3**, **L4**, and **L5**, sacrum **16**, and brain **18**, including cerebellum **20**. **FIG. 1** also illustrates as sheath **24** a medical device suited for attachment to skin **22**,

which includes elongated member **26**, first end **28**, second end **30**, skin-attachment apparatus **32**, valve apparatus **36** coupled to first end **28**, and flush line **38**. As used in this document (including the claims), "elongated" simply means having a length. Skin-attachment apparatus **32** includes flexible skin-attachment flap **34** configured for attachment (and actually attached as shown) to skin **22**. Further, skin-attachment apparatus **32** is configured to be coupled to elongated member **26** at a location along elongated member **26** described in this document (including the claims) as a "coupling location." **FIG. 1** illustrates that skin-attachment apparatus **32** and valve apparatus **36**, which are both coupled to elongated member **26**, define flexible member portion **40** between them.

As shown in **FIG. 1**, elongated member **26** includes a first passageway that is sized to slidably receive, and work with, at least a guidewire. In this document (including the claims), a passageway that is "sized to slidably receive, and work with, at least a guidewire" means that the passageway is configured for use in normal operation with a medical device that can be the size of at least a guidewire. Thus, a passageway so sized is configured for use in normal operation with a guidewire, and may also be configured for use in normal operation with larger medical devices, including certain sheaths, catheters, and dilators. As shown in **FIG. 1**, another device having a first passageway that is sized to slidably receive, and operate with, at least a guidewire is illustrated as catheter **42**, which has been percutaneously introduced into subarachnoid space **14** at entry location **50** through the first passageway of elongated member **26**. Guidewire **44** is shown in **FIG. 1** as having been percutaneously introduced into subarachnoid space **14** at entry location **50** through the first passageways of both catheter **42** and elongated member **26**. As used in this document (including the claims), "introducing a device into the subarachnoid space" means causing the device to pass through the boundary that defines the spinal subarachnoid space. The boundary need not be physical, so the device does not need to be in contact with the subarachnoid space. Thus, and for example, passing a guidewire or a catheter through the passageway in a sheath that is positioned within the subarachnoid space amounts to introducing that guidewire or catheter into the subarachnoid space so long as that guidewire or catheter passes across the boundary that defines where the subarachnoid space begins. Furthermore, as used in this document

(including the claims), "percutaneously introducing" a device means to introduce the device without first cutting away bone through, for example, craniotomy or drilling burr holes.

Prior to percutaneously introducing sheath **24** into subarachnoid space **14** at entry location **50**, an operator may direct a guidewire through skin **22** and dural membrane **10** and into subarachnoid space **14**, and more specifically the spinal subarachnoid space, in order to facilitate the introduction of sheath **24**. This guidewire introduction may be achieved, for example, by directing a needle through the skin and the dural membrane between any of the lumbar vertebrae. The spaces between adjacent vertebrae are known as interspaces, such as the **L1-2** interspace labeled as element **46**.

While **FIG. 1** illustrates introduction into the subarachnoid space (and specifically into the spinal subarachnoid space) in the lumbar region, entry locations may be made in other regions, including the thoracic and cervical regions of the spine. Thus, devices such as catheters, sheaths, and guidewires (including those illustrated in **FIG. 1**) may pass through the following interspaces: C1-2, C2-3, C3-4, C4-5, C5-6, C6-7 (i.e., the cervical interspaces), T1-2, T2-3, T3-4, T4-5, T5-6, T6-7, T7-8, T8-9, T9-10, T10-11, and T11-12 (i.e., the thoracic interspaces). With the needle in place, a guidewire may be introduced into the spinal subarachnoid space through a passageway (sometimes referred to as a "lumen") within the needle. The guidewire may then be directed superiorly and advanced within the spinal subarachnoid space and toward the patent's head to a desired location. The position of the guidewire within the patient, including within the various regions of the subarachnoid space, may be monitored using any suitable imaging modality, such as magnetic resonance imaging, fluoroscopy, endoscopy, computed tomography, thermal imaging, sonography, or any combination of these. Moreover, these imaging modalities can be used throughout a procedure to monitor the various positions of other medical devices, provided that the right conditions exist (such as sufficient radiopacity, etc.)

After introducing a guidewire, such as guidewire **44**, into the subarachnoid space, the operator may dilate the tract created by the guidewire using one or more medical devices suited for that purpose, such as dilators. This may be done after removing the

needle. Alternatively, a suitably structured sheath may be introduced over the guidewire for the same dilation purpose and also to facilitate intracranial access with a second device introduced through the passageway of the sheath. If an operator uses a dilator, a medical device such as sheath **24** may be passed over the dilator, and the dilator can then be removed through the passageway of the sheath.

Following sheath placement, techniques applied during procedures such as angiography may be used to navigate the subarachnoid space, including the spinal and intracranial subarachnoid spaces. In this regard, another guidewire may be introduced through the sheath and into the subarachnoid space with a tip that is directed either anteriorly or posteriorly in relation to the spinal cord. A medical device such as a catheter may then be introduced over the guidewire to facilitate intracranial access using a device introduced through the passageway of the catheter.

The navigation described above, including one or more of the steps for introducing the various medical devices into the subarachnoid space and advancing those devices within the subarachnoid space and, sometimes, toward the head of the patient, may be achieved in whole or in part using a robotic device. Furthermore, the representative applications of the present methods discussed below may be carried out in whole or in part using a robotic device. Potential advantages of using a robotic device in this fashion pertain, for example, to navigating through neural tissue. The pial membrane surrounding the brain forms a barrier to penetration, and once the membrane is punctured, there is essentially no resistance to navigation offered by cerebral tissue. Using a robotic device to assist with navigation of the cerebral tissue may be beneficial given the great extent to which the movements of a catheter or guidewire can be controlled using a robotic device and viewed using an imaging modality.

Turning next to **FIG. 2A**, an enlarged view of a small portion of the central nervous system is illustrated, and sheath **24** is shown positioned within the subarachnoid space **14**. As shown in **FIG. 2A**, subarachnoid space **14** is the spinal subarachnoid space. The spinal subarachnoid space is located within the bony canal created by the vertebrae and is different than the intracranial subarachnoid space, which is located above the foramen magnum, as described above. As shown, sheath **24** was percutaneously

introduced into the spinal subarachnoid space through dural membrane **10** at entry location **50**, and subsequently advanced through the spinal subarachnoid space and toward the head of the patient to facilitate intracranial access by both catheter **24** and guidewire **44**. Skin-attachment apparatus **32**, which is configured to be coupled to and, in fact, is coupled to, elongated member **26** of sheath **24**, is shown as being attached to skin **22** using sutures **54** (only one of which is shown) placed through openings **56** (only one of which is shown) in flexible skin-attachment flap **34**. Securing mechanism **52** is shown in **FIG. 2A** as being used with skin-attachment apparatus **32** to secure the position of skin-attachment apparatus **32** along elongated member **26**. Advantageously, the coupling location of skin-attachment apparatus **32** to elongated member **26** may vary, thereby increasing the versatility of sheath **24** by comparison to sheaths with fixed skin-attachment apparatuses. Furthermore, by spacing apart skin-attachment apparatus **32** from valve apparatus **36**, flexible member portion **40** is defined between the two.

Flexible member portion **40** affords the operator many advantages because it gives him/her the ability to introduce devices through the one or more passageways of sheath **24** at a location that is remote (i.e., spaced apart) from both the location at which the sheath is attached to the skin and the location at which the sheath enters the skin. For example, some patient motion during the operation can be absorbed by flexible member portion **40**. Also, because the length of flexible member portion may be adjusted, the operator can position him or herself remotely from the patient when performing the various steps of the present methods and while permitting the position of various instruments to be monitored via imaging modalities such as magnetic resonance imaging (MRI). Thus, having a suitable length, flexible member portion **40** will allow extension of elongated member **26** from the area of the patient that will be inaccessible during placement of the patient in an MR scanners.

The length of the present flexible member portions, and the distance between one of the present skin-attachment apparatuses and the first end of one of the present elongated members (which distance will differ from the length of the present flexible member portion based on the length of the valve apparatus in question) can be any distance suited to the particular operation, including 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10, 10.5, 11, 11.5, 12, 12.5, 13, 13.5, 14, 14.5, 15, 15.5, 16, 16.5,

17, 17.5, 18, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26, 26.5, 27, 27.5, 28, 28.5, 29, 29.5, 30, 30.5, 31, 31.5, 32, 32.5, 33, 33.5, 34, 34.5, 35, 35.5, 36, 36.5, 37, 37.5, 38, 38.5, 39, 39.5, 40, or more centimeters. Additional suitable distances include 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, and 70 centimeters, or even more if the particular application warrants further removal of the operating physician from the insertion point in the skin. Furthermore, the length of flexible member portion **40** can be adjusted to suit the use of sheath **24** with a robotic device.

Moving to **FIG. 2B**, it shows a view similar to that depicted in **FIG. 2A**. Specifically, **FIG. 2B** illustrates sheath **24**, which has been percutaneously introduced into subarachnoid space **14** (which, as shown, is spinal subarachnoid space) at entry location **50**. From entry location **50**, sheath **24** has been advanced (as shown by the dotted lines) a distance from that entry location to a second location **51**. This distance is illustrated in **FIG. 2B** in terms of **D1**, which is the distance along the path taken by sheath **24**. **D1** can be determined by measuring the length of sheath **24** advanced beyond entry location **50**. This distance is also illustrated in terms of **D2**, which is the straight-line distance between entry location **50** and second location **51**. This distance is also illustrated as **D3**, which is the absolute distance toward the head that sheath **24** has been advanced between entry location **50** and second location **51**. **D3** can be determined by measuring the distance between a plane intersecting entry location **50** and oriented substantially laterally across the longitudinally-oriented patient and a plane intersecting second location **51** and oriented substantially laterally across the longitudinally-oriented patient.

In this document (including the claims), advancing a device a distance from an entry location means that the device is advanced a distance consistent with any of **D1**, **D2**, and **D3**. Thus, advancing a device at least greater than 10 centimeters from an entry location means that the device is advanced at least more than 10 centimeters (e.g., any distance that is greater than 10 centimeters, including 10.1 centimeters, etc.) according to the distance along the path taken by the device (i.e., **D1**), that the device is advanced at least more than 10 centimeters according to the straight-line distance from the entry location (i.e., **D2**), or that the device is advanced at least more than 10 centimeters

according to the absolute distance in the direction of advancement from the entry location (i.e., **D3**). Suitable distances that the devices disclosed herein that have passageways sized to slidably receive, and operate with, at least a guidewire (such as sheath **24** and catheter **42**) may be advanced within the spinal subarachnoid space from the entry location of the device consistent with the present methods include 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10, 10.1, 10.2, 10.3, 10.4, 10.5, 10.6, 10.7, 10.8, 10.9, 11, 11.5, 12, 12.5, 13, 13.5, 14, 14.5, 15, 15.5, 16, 16.5, 17, 17.5, 18, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26, 26.5, 27, 27.5, 28, 28.5, 29, 29.5, 30, 30.5, 31, 31.5, 32, 32.5, 33, 33.5, 34, 34.5, 35, 35.5, 36, 36.5, 37, 37.5, 38, 38.5, 39, 39.5, 40, or more centimeters. Furthermore, distances that the devices disclosed herein that have passageways sized to slidably receive, and operate with, at least a guidewire (such as sheath **24** and catheter **42**) may be advanced within the spinal subarachnoid space consistent with the present methods and that are greater than at least 10 centimeters from the entry location of the device include 10.1, 10.2, 10.3, 10.4, 10.5, 10.6, 10.7, 10.8, 10.9, 11, 11.5, 12, 12.5, 13, 13.5, 14, 14.5, 15, 15.5, 16, 16.5, 17, 17.5, 18, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26, 26.5, 27, 27.5, 28, 28.5, 29, 29.5, 30, 30.5, 31, 31.5, 32, 32.5, 33, 33.5, 34, 34.5, 35, 35.5, 36, 36.5, 37, 37.5, 38, 38.5, 39, 39.5, 40, or more centimeters. Further still and consistent with the present methods, the devices disclosed herein that have passageways sized to slidably receive, and operate with, at least a guidewire (such as sheath **24** and catheter **42**) may be advanced within the spinal subarachnoid space distances from the entry locations of the devices greater than at least 11, 11.5, 12, 12.5, 13, 13.5, 14, 14.5, 15, 15.5, 16, 16.5, 17, 17.5, 18, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26, 26.5, 27, 27.5, 28, 28.5, 29, 29.5, 30, 30.5, 31, 31.5, 32, 32.5, 33, 33.5, 34, 34.5, 35, 35.5, 36, 36.5, 37, 37.5, 38, 38.5, 39, 39.5, 40, or more centimeters.

FIG. 3 illustrates a top view of sheath **24**. As illustrated in a cut-away section of **FIG. 3**, elongated member **26** has a first passageway **58** that is sized to receive, and work with, at least a guidewire. Valve apparatus **36**, which is configured to be coupled to and, in fact, is coupled to first end **28** of elongated member **26**, provides a membrane **60** that extends across first passageway **58** in a way that allows other devices to be introduced through passageway **58** while preventing fluid from flowing out of sheath **24** through first

end **28**. Within this document (including the claims), a "valve apparatus" is any apparatus that, when coupled (either directly or indirectly) to elongated member **26**, is capable of sealing one or more of the passageways (such as first passageway **58**) of elongated member **26** against fluid trying to flow out through the particular passageway in a direction out of a patient. Although membrane **60** is shown as extending across first passageway **58** at a location within first passageway **58**, those of skill in the art having the benefit of this disclosure will understand that membrane **60** could also be positioned outside of first passageway **58** and achieve the same function. For example, although not shown, those of skill in the art having the benefit of this disclosure will understand that membrane **60** could be formed as a rubber gasket situated between two elements that screw into each other and vary an opening within membrane **60**, thereby providing an adjustable opening valve. Valve apparatus may be coupled to elongated member **26** using any suitable means, including a threaded connection, friction fit, interlocking parts, a clamp, glue, integral formation or other means of permanent attachment, or the like. In addition, valve apparatus **36** may be configured, as it is in **FIG. 3**, to allow for attachment of flush line **38**. This may be accomplished in any conventional fashion, including through the use of a protrusion that is formed as part of valve apparatus **36** and extends away from it (not shown) to which a flush line may be coupled. Valve apparatus **36** may also be configured to allow for fluid communication between flush line **38** and first passageway **58**. Alternatively, valve apparatus may also be configured to allow for fluid communication between flush line **38** and a passageway within elongated member **26** other than first passageway **58**. Furthermore, valve apparatus **36** may be configured with hub **62** that is configured for attachment to other medical devices such as guidewires, sheaths, catheters, and introducers. The hub may, for example, take the form of a male or female Luer lock piece.

Although only one skin-attachment apparatus **32** is illustrated in the present figures, certain operations may benefit from the use of two or more such apparatuses. Accordingly, two, three, four, five, or more skin-attachment apparatuses configured to be coupled to elongated member **26** may be coupled to and used with elongated member **26**. Each of these skin-attachment apparatuses may be coupled to elongated member **26** at coupling locations spaced apart from the ends of elongated member **26**. One combination

of skin-attachment apparatuses includes permanently attaching one to elongated member **26**, and coupling another skin-attachment apparatus in between the permanently-attached skin-attachment apparatus and a valve apparatus coupled to the first end of the elongated member such that the coupling location of the second skin-attachment apparatus is variable. Furthermore, each skin-attachment apparatus may have a flexible skin-attachment flap that is configured for attachment to the skin of a patient. In this regard, while openings **56** are shown in flexible skin-attachment flap **34** for attaching the flexible skin-attachment flap to the skin of a patient, it will be understood that any suitable manner of configuring the flap for attachment to the skin may be used, including the use of a temperature sensitive adhesive, a repositionable adhesive, clips (such as small alligator clips), tape, glue, and the like.

FIGS. 4-9 show different embodiments of skin-attachment apparatus **32**. In **FIG. 4**, skin-attachment apparatus **32**, which is configured to be coupled to elongated member **26** at a coupling location and which includes flexible skin-attachment flap **34** , is coupled to elongated member **26** such that it is permanently attached to elongated member **26**. This may be accomplished by securing flexible skin-attachment flap **34** to elongated member **26** through gluing, integral formation, or the like.

FIG. 5 shows skin-attachment apparatus **32** coupled to elongated member **26** in a way that permits the coupling location of skin-attachment apparatus to elongated member **26** to vary prior to or after attachment of skin-attachment apparatus to a patient's skin. Specifically, skin-attachment apparatus **32** includes flexible skin-attachment flap **34**, secondary flap **66**, and securing mechanisms **52**, which serve to tighten the flaps against elongated member **26** when the mechanisms are engaged. Securing mechanisms may take the form of clips (such as small alligator clips), clamps, flaps that snap together, string, or any other suitable means of temporarily securing flaps **34** and **66** around elongated member **26** in a way that prevents elongated member **26** from moving relative to the flaps until securing mechanisms **52** are disengaged. Padding material, such as a sponge, gelatin-like material, or trapped air may be placed in spaces **68** defined by flaps **66**, **34**, and elongated member **26**, in order to make attachment of skin-attachment apparatus **32** more comfortable to patients placed in supine positions.

FIGS. 6 – 8 show skin-attachment apparatuses **32** coupled to elongated member **26** using only one securing mechanism **52**. In addition, skin-attachment apparatus **32** in **FIG. 6** includes adhesive **70**, instead of openings **56** shown in other figures, that is useful in attaching flexible skin-attachment flap **34** to a patient's skin. In **FIG. 7**, flexible skin-attachment flap **34** contains padding material **72** (as may any of the present flexible skin-attachment flaps), which is useful as described above. In both **FIGS. 6** and **7**, flexible skin-attachment flaps **34** are positioned between elongated member **26** and securing mechanisms **52**. In contrast, **FIG. 8** shows that securing mechanism **52** may be in direct contact with elongated member **26**. In the embodiment shown in **FIG. 8**, flexible skin-attachment flap **34** may be secured to securing mechanism **52** using any suitable means, including glue, integral formation, and the like.

Although not shown in **FIGS. 4-9**, it should be understood that a flexible skin-attachment flap **34** may be configured in the form of a flap that is folded over elongated member **26** and snapped together, the mating snaps serving as securing mechanism **52**.

Turning to **FIG. 9**, the embodiment of skin-attachment apparatus **32** shown includes padding material **72** within flexible skin-attachment flap **34**, and may include the same in space **68**. Flaps **66** and **34** shown in both **FIG. 5** and **FIG. 9** may be attached to each other using any suitable means described in this document.

FIGS. 10, 11 and **12** illustrate different embodiments of elongated member **26** of sheath **24**. While these figures are described in terms of elongated member **26** and, hence, sheath **24**, the embodiments discussed are equally applicable to devices such as catheter **42** depicted in **FIG. 1**, which may be introduced through the passageways discussed in **FIGS. 10-12**.

FIG. 10 illustrates a cross section of elongated member **26**, revealing that it can have a shape at a given cross section that is non-circular. Advantageously, an elongated member **26** having such a shape along any portion of its length may be well-suited to navigating certain regions within the subarachnoid space that are wider in one dimension than in another. Suitable shapes of cross sections taken at a particular location along an elongated member include oval, and figure-eight shapes. Furthermore, the present

elongated members, and the present sub-elongated members discussed below, may have cross-sectional shapes that vary along the length of the member.

FIG. 11 illustrates another cross section of elongated member **26**, revealing that it can have both first passageway **58** and second passageway **74**. Like first passageway **58**, second passageway **74** can be sized to slidably receive, and work with, at least a guidewire. Moreover, elongated member **26** can have additional such passageways consistent with the present methods and apparatuses. Additionally, while the passageways described in this document (including the claims) may extend through openings that coincide with the ends of the particular devices in question (such as sheath **24** and catheter **42** shown in **FIG. 1**), the openings within the present medical devices that serve to define the present passageways may be located in positions other than the ends of the present medical devices. Thus, a sheath or a catheter that has one or both ends closed may nevertheless have a passageway as that term is used in this document (including the claims) so long as two openings to the outside of the device exist that serve to define the passageway. For example, one of the present devices could have a passageway defined by openings positioned within the wall of the device. In addition, two passageways could share a common opening, regardless of the location of the common opening. However, if the passageway in question is restricted to being sized to slidably receive, and work with, at least a guidewire, the positioning of the openings in question must satisfy this condition as well.

Turning next to **FIG. 12**, there is shown elongated member **26** having two sub-elongated members **76** and **78** that are coupled together using coupling device **80**, which allows the operator to snap the pieces of tubing together. Other means for coupling sub-elongated members **76** and **78** may also be used, such as interlocking parts that are integrally formed with the sub-elongated, interlocking parts that are attached to the sub-elongated members, adhesives that serve to secure the sub-elongated members together but that allow them to be repositioned and re-secured, melting of the sub-elongated members together, glue, and the like. Alternatively, sub-elongated members **76** and **78** may be joined, as by bonding during manufacture, such that a cross-sectional configuration of them resembles that shown in **FIG. 12**, only without a coupling device **80** interposed between sub-elongated members **76** and **78**. Sub-elongated member **76** has

first passageway **58**, and sub-elongated member **78** has second passageway **74**. In this document (including the claims), "a sub-elongated member" can, but need not, have a perfectly round cross section. Thus, both sub-elongated members **76** and **78** could have cross sections at any location along their length with shapes like the ones depicted in **FIG. 10**.

Furthermore, as shown in **FIG. 13A**, sheath **24** can include elongated member **26**, which can have sub-elongated members **76** and **78** that possess different lengths. As shown, sub-elongated member **76** has first end **28** and second end **30**, and sub-elongated member **78** has first end **82** and second end **84**. **FIG. 13A** also shows that valve apparatus **36** may be coupled to both sub-elongated members, as may be skin-attachment apparatus **32**. Furthermore, end **84** is closed, and sub-elongated member **78** has an opening **86** located within the wall of sub-elongated member **78** that together with the opening at first end **82** of sub-elongated member **78** serves to define second passageway **74**.

Moving ahead to **FIG. 13H**, the same shows that the sub-elongated members of sheath **24** depicted in **FIG. 13A** may alternatively be arranged such that one of the sub-elongated members has multiple openings **86**, as shown in sub-elongated member **76**. Sub-elongated member **76** has a closed second end **30** in **FIG. 13H**. As explained below, fluid may be introduced through one passageway to a desired location, and withdrawn through another passageway. The configuration of sheath **24** illustrated in **FIG. 13H** may be used during such a procedure.

FIGS. 13B-G illustrate different embodiments of the shapes of second ends **30** and **84** of sub-elongated members **76** and **78**, respectively. **FIG. 13B** shows that second end **30** of sub-elongated member **76** may be offset from second end **84** of sub-elongated member **84**. **FIG. 13B** also shows that second end **30** of sub-elongated member **76** may be beveled, or tapered, into sub-elongated member **80**, thereby reducing the chance that sheath **24** will "hang up" on other structures prior to reaching its intended destination. This same benefit may be realized using the configuration of sheath **24** (via sub-elongated members **76** and **78**) shown in **FIGS. 13C**, **13D**, and **13G**. The configurations illustrated in **FIGS. 13E** and **13F** may be used as the application warrants.

Currently, catheters are available that have compound wall constructions that impart a variable stiffness along the length of the catheter. Catheters are also available with reinforcing material braided into the wall of the catheter to give the catheter greater strength and resistance to kinking. The present devices such as catheter **42** and sheath **24** may have lengths and stiffnesses that vary along those lengths, and they may have walls that include braided materials therein. Also, the present devices such as catheter **42** and sheath **24** may be bendable, and may retain a shape after being bent.

As those of skill in the art will understand, the size of a given passageway of one of the present devices (such as sheath **24** or catheter **42**) may be sized appropriately for a given application. Diameters for a passageway within a given device (such as sheath **24**, and specifically elongated member **26**, and catheter **42**) may, for example, be chosen from sizes that include 0.008, 0.009, 0.010, 0.011, 0.012, 0.013, 0.014, 0.015, 0.016, 0.017, 0.018, 0.019, 0.020, 0.021, 0.022, 0.023, 0.024, 0.025, 0.026, 0.027, 0.028, 0.029, 0.030, 0.031, 0.032, 0.033, 0.034, 0.035, 0.036, 0.037, 0.038, 0.039, 0.040, 0.041, 0.042, 0.043, 0.044, 0.045, 0.046, 0.047, 0.048, 0.049, 0.050, 0.051, 0.052, 0.053, 0.054, 0.055, 0.056, 0.057, 0.058, 0.059, 0.060, 0.061, 0.062, 0.063, 0.064, 0.065, 0.066, 0.067, 0.068, 0.069, 0.070, 0.071, 0.072, 0.073, 0.074, 0.075, 0.076, 0.077, 0.078, 0.079, 0.080, 0.081, 0.082, 0.083, 0.084, 0.085, 0.086, 0.087, 0.088, 0.089, 0.090, 0.091, 0.092, 0.093, 0.094, 0.095, 0.096, 0.097, 0.098, 0.099, and 0.10 inches. These same dimensions may, for example, serve as the size of either the widest or most narrow dimension of a passageway of one of the present devices (such as sheath **24**, and specifically elongated member **26**, and catheter **42**) that has a non-circular shape. The outer diameter of the present devices (such as sheath **24**, and specifically elongated member **26**, and catheter **42**) may, for example, be chosen from sizes that include 1, 2, 3, or 4 millimeters. These same dimensions may, for example, serve as the size of either the widest or most narrow dimension of the outer surface of one of the present devices (such as sheath **24**, and specifically elongated member **26**, and catheter **42**) that has a non-circular shape.

As explained with reference to **FIG. 1**, for example, the present devices (such as sheath **24** and catheter **42**) enter the spinal subarachnoid space after passing through dural membrane **10**. In order to close dural membrane **10** after a procedure is complete, the present devices (such as sheath **24**, and specifically elongated member **26**, and catheter

42) may have a dural closure apparatus coupled to it. The dural closure apparatus may be configured to be coupled to the device in question, and, in fact, may be coupled to it. The dural closure apparatus may be configured to close the dural membrane as the device is withdrawn from the spinal subarachnoid space. In one embodiment, the dural closure apparatus may be configured to effect closure through movement of a needle, or other suture-delivering apparatus, that is actuated by the operator to cause a suture to be placed through the dura. In another embodiment, the dural closure apparatus may be configured to effect closure through injection of a chemical compound that seals the hole in the dura after the device is withdrawn. One example of a dural closure apparatus that may be modified and coupled to one of the present devices is THE CLOSER (commercially-available from Perclose, Inc., an Abbot Laboratories Company, 400 Saginaw Drive, Redwood City, CA 94063).

FIG. 19 illustrates an embodiment of sheath **24** (which, of course, is equally applicable to catheter **42**) in which sub-elongated elements **76** and **78** exist, wherein braiding material **130** (which can be a wire) is wrapped around both sub-elongated elements along the length of the sub-elongated elements (the total length not being shown). Such wrapping appears as a figure eight when viewed from the top. The braiding material may be wrapped as tightly or as loosely as the application warrants, and the tightness of the wrapping may vary along the length of sheath **24**, thereby imparting the sheath with a variable stiffness and, therefore, flexibility. The same type of wrapping may be applied to a catheter having only one passageway, as illustrated in **FIG. 20**. There, the wrapping may be achieved using a single wire that is placed in contact with the wall of catheter **42** at roughly the mid-point **132**. Then, the two halves of braiding material **130** may be crisscrossed to achieve the desired braiding, varying the tightness of the wrapping as desired to affect the stiffness of catheter **42**. Alternatively, one end of braiding material may be placed in contact with catheter **42** near the end shown in **FIG. 20**, and the braiding may be achieved by winding the free end of the braiding material once around the catheter, then back up so as to cross the already-formed loop, then back down slightly further, and back up in the same fashion, repeating the process to achieve the desired braiding. Again, the tightness of the wrapping (which may be thought of as

the closeness of the braiding material segments to each other) may be varied to vary the stiffness of the catheter.

The braiding pattern used may affect the MR-visibility of the resulting catheter or sheath. The subarachnoid space is filled with CSF that is relatively static and is of very high signal intensity on T2-weighted images. While a material that presents a signal void on MR could not be seen on either TI- or T2-weighted fluoroscopy in the vascular space (flowing blood has a signal void in either of these settings), a material that has a signal void is very conspicuous on T2-weighted imaging in the subarachnoid space. Platinum is a metal that is appropriate for enhancing the MR-visibility of the present devices. Additionally, other metals having low signal intensity may be appropriate. For example, there is a non-ferromagnetic form of stainless steel that is used in some needles for biopsy under MR guidance (Cook, Inc.). Also, there is an alloy of nickel and titanium (nitinol) that is used for guidewires and has been used in catheter braiding in the past (Target Therapeutics) that may have desirable signal characteristics. These materials may be used as markers on the present devices, and for braiding material **130**. In addition, stainless steel, which is currently used in some catheter braiding by Cordis, may be used as braiding material **130**. Kevlar may also be used for braiding material **130**.

Medical devices such as sheaths and catheters that have the configurations discussed in **FIGS. 11** and **12** (i.e., that have two or more passageways) may enable the use of an endoscope in one passageway to observe, for example, a manipulation conducted using a device introduced through the other passageway, or even the position of the other sub-elongated member that has the other passageway. Medical devices such as sheaths and catheters that have the configurations discussed in **FIGS. 11** and **12** (i.e., that have two or more passageways) may also permit a fluid to be introduced in one passageway and withdrawn via the other passageway. Medical devices such as sheaths and catheters that have the configurations discussed in **FIGS. 11** and **12** (i.e., that have two or more passageways) may allow the introduction of a guidewire in one passageway and another, therapeutic device in the other passageway. Interaction between functions conducted via each passageway may be achieved such that the functions work together, or compliment each other, to achieve a therapeutic goal.

Furthermore, medical devices such as sheaths and catheters that have the configurations discussed in **FIGS. 11** and **12** (i.e., that have two or more passageways) have vascular applications, too. For example, there are currently instances in aneurysm treatment in which one catheter is introduced via one femoral artery for placement within an aneurysm and another catheter is introduced via the other femoral artery for introduction of a balloon across an aneurysm neck. Using a device other than a balloon to assist the aneurysm coiling, an apparatus may be introduced via one passageway of a medical device such as a sheath or catheter that has one of the configurations discussed in **FIGS. 11** and **12** (i.e., that has two or more passageways) to improve an aneurysm neck while a coil is introduced via the other passageway, thus achieving via a single femoral artery access that currently requires bilateral access. Furthermore, this aneurysm embolization may be achieved using a sheath or catheter that includes 2 sub-elongated members whose distal portions are spaced apart from each other, as in a "Y" shape.

FIG. 18 illustrates a penetration apparatus **120** that is useful in penetrating various membranes that may be encountered using the present methods. Penetration apparatus **120** includes outer sleeve element **122**, outer sleeve element hub **124** coupled to outer sleeve element **122**, inner puncture element **126**, and inner puncture element hub **128** coupled to inner puncture element **126**. Outer sleeve element hub **124** may be configured to be slidably coupled to inner puncture element **126** (such that outer sleeve element **122** may slide along, and then be locked against, inner puncture element **126**), and inner puncture element hub **128** may be configured to be slidably coupled to another device introduced through the passageway (not shown) of inner puncture element **126**. Inner puncture element may be provided with a passageway sized to slidably receive, and operate with, at least a guidewire.

One membrane that may be punctured by operating penetration apparatus **120** is the pia matter - a membrane surrounding the brain that is fragile in some locations and tough in others. Distal tip **130** of inner puncture element may be configured to be sharp enough to penetrate the pia matter at any location therealong without exerting a degree of force or manipulation that results in either tearing of brain tissue or distortion of brain tissue prior to penetration. In operation, a device (such as sheath **24** or catheter **42**) may be percutaneously introduced into the spinal subarachnoid space at an entry location, the

device having a first passageway sized to slidably receive, and operate with, at least a guidewire; the device may be advanced within the subarachnoid space at least more than 10 centimeters from the entry location, or to facilitate intracranial access with a second device introduced through the first passageway; penetration apparatus **120** may be advanced through the first passageway of the device, and a membrane, such as the pia matter, may be punctured using penetration apparatus **120**. More specifically, penetration apparatus **120** may be advanced along a guidewire, or it may simply be advanced through the first passageway, to the edge of the membrane; inner puncture element **126** may be further advanced until it punctures the membrane; inner puncture element may then be retracted into outer sleeve element **122** and penetration apparatus **120** advanced through the plane of the punctured membrane, or outer sleeve element **122** may be advanced over inner puncture element **126** through the plane of the punctured membrane. Outer sleeve element **122** may then act as a guidewire for a device such as catheter **42** as the same advances into the brain substance.

The material that may be used for the inner and outer elements of penetration apparatus **120** may, for example, be metallic or polymeric, such as plastic. Suitable materials for both outer sleeve element **122** and inner puncture element **126** include a nickel-titanium alloy, such as nitinol, that is treated to enhance its radiopacity. Alternatively, stainless steel may be used for either element, which can be plated with gold or platinum to enhance radiographic visibility. If an imaging modality such as MRI or radiographic visualization (e.g., fluoroscopy), that imaging modality used may impact the materials used in the construction of the elements of penetration apparatus **120**.

Another embodiment of penetration apparatus **120** that is not shown in **FIG. 18** differs from the embodiment shown in **FIG. 18** in the manner in which the inner and outer elements **126** and **122** are interrelated. In this additional embodiment, inner puncture element **126** is coupled to outer sleeve element **122** with a mechanism that allows inner puncture element to be "fired," or advanced rapidly, a few millimeters to achieve rapid penetration. In yet another embodiment of penetration apparatus **120** not shown in **FIG. 18**, inner puncture element **126** is coupled to outer sleeve element **122** using threads to allow for finely-controlled advancement of inner puncture element **126**.

The present methods will offer many advantages over conventional methods of surgically accessing the intracranial and spinal subarachnoid space, which have historically consisted of the skin incision, dissection to either the cranium or spinal bony covering, removal of some bone, and dissection through the meninges to gain access to the neurological structures. For example, the present methods will avoid a craniotomy and a brain retraction, which are typical for conventional approaches to brain surgery; the present methods will enable operators to surgically approach the brain from a remote location (such as from a lumbar puncture, for instance); they will make it possible to perform such surgery in an MR scanner without interference from magnets in the surgical field; they will allow access to areas of the brain that are difficult to reach from a craniotomy approach; and the present methods it may enable some types of procedures (subarachnoid space lavage, etc.) not easily performed via craniotomy.

Representative applications of the present methods

The following representative applications may be performed using devices such as catheter **42** and sheath **24**, and further using any embodiment of those devices depicted in **FIGS. 1** and **10-13H**. Thus, anytime that a device such as catheter **42** or sheath **24** is referenced below in relation to the representative applications, it will be understood that versions of that device depicted in **FIGS. 10-13H** may be used for the given application. Depending on the application, the devices used may be treated so as to maximize their visibility via a given imaging modality, such as MRI or radiography (e.g., fluoroscopy).

Furthermore, it will be understood that for a given application, it may be feasible to introduce one device into the subarachnoid space at one entry location, and later, or simultaneously, introduce another device into the subarachnoid space at a different entry location, thereafter using the devices together to achieve a therapeutic result. For example, in altering the temperature of at least some brain tissue, discussed below in greater detail, it may be possible to introduce a fluid through the passageway of one device introduced into the subarachnoid space (such as the spinal subarachnoid space) at one entry location, and withdrawing fluid through the passageway of another device introduced into the subarachnoid space (such as the spinal subarachnoid space) at another entry location. As another example, in flushing CSF as described below, it may be

beneficial to use two passageways of a sheath or catheter having multiple passageways to deliver fluid to a target area. Further, this may be achieved using a sheath or catheter that includes 2 sub-elongated members whose distal portions are spaced apart from each other, as in a "Y" shape. Fluid may be withdrawn through the passageway of a device introduced at a different entry location, or fluid may be withdrawn through a third passageway within the sole sheath or catheter.

flushing of cerebrospinal fluid to help alleviate vasospasm

The present methods can be used in the treatment of subarachnoid hemorrhage. A major complication of subarachnoid hemorrhage is vasospasm, which is related to the presence of blood in the subarachnoid space surrounding cerebral blood vessels. One treatment that is used neurosurgically to help alleviate vasospasm entails the lavage of the cerebrospinal fluid within the subarachnoid space with both saline and with hemolytic agents to remove the blood. Using the present methods, it may be feasible from a percutaneous spinal approach to catheterize the subarachnoid space in the region of a hemorrhage or clot and perform lavage from that approach without craniotomy. For example, after introducing a device (such as sheath **24** or catheter **42** discussed in relation to **FIG. 1**) into the spinal subarachnoid space at an entry location, the device having a passageway sized to slidably receive, and work with, at least a guidewire, and after advancing that device within the spinal subarachnoid space a distance from the entry location, saline and/or material having hemolytic agents may be transferred through the passageway of the device toward the region of the hemorrhage or clot in order to flush the relevant cerebrospinal fluid. This flushing may also be achieved with a second device introduced through the passageway of the first device.

modifying the temperature of at least some brain tissue

The present methods can be used to modify the temperature of at least some brain tissue. Such a modification may be achieved by flushing selected brain tissue with a fluid that may be temperature-controlled, such as saline, which fluid is introduced through a device introduced into the spinal subarachnoid space. For example, after introducing a device (such as sheath **24** or catheter **42** discussed in relation to **FIG. 1**) into the spinal subarachnoid space at an entry location, the device having a passageway sized to slidably

receive, and work with, at least a guidewire, and after advancing that device within the spinal subarachnoid space a distance from the entry location, the temperature of at least some brain tissue may be modified by introducing a temperature-controlled fluid, such as saline, through the passageway of the device to the selected brain tissue. This may be particularly effective using a device that has at least two passageways. The introduction of fluid in this manner may also be achieved with a second device introduced through the passageway of the first device.

One example of modifying the temperate of at least some brain tissue is inducing hypothermia in at least some brain tissue. The potential beneficial effects of hypothermia in protection against injury are well known, both in the public domain and in the medical literature. The most commonly encountered instance in the uncontrolled environment is probably in near drowning. In these situations, survival is enhanced in cold water because the metabolism is slowed and hypoxia is better tolerated.

In neurosurgical practice, hypothermia is used therapeutically to prolong cerebral vascular occlusion times that can be tolerated during aneurysm surgery. However, most traditional neurosurgical techniques are unable to create isolated cerebral hypothermia. Thus, whole-body hypothermia is used, often in association with circulatory arrest, with all the attendant risks.

A pumping apparatus may be utilized in the process of modifying the temperature of at least some brain tissue to assist in maintaining pressures and temperatures within the subarachnoid space. This pumping apparatus may be coupled to the device through which the fluid is introduced. This pumping apparatus may include 2 independently-controlled, calibrated pumps that may be coupled to a hub adapter coupled to, for example, the device through which the fluid is introduced. To control the intracranial fluid volume, the volume of fluid pumped into the subarachnoid space may be matched by an equal volume that is withdrawn from the subarachnoid space. This pumping apparatus may be configured to achieve this balance with flow monitors and flow controls, even in circumstances in which the outflow may be achieved without introducing negative pressure at the outflow site. Further, in this regard, this pumping apparatus may be configured to operate with pressure monitors and pressure controls that

enable both the measurement of intracranial pressures and the manipulation of the same. In addition, this pumping apparatus may be configured to operate with temperature monitors and temperature controls that enable both the measurement of intracranial temperatures and the manipulation of the same. In this regard, the pumping apparatus may be configured to operate with temperature monitors and temperature controls that enable both the measurement of infused fluid temperatures and the manipulation of the same.

Flow rates as low as a fraction of a cubic centimeter per second or as high as multiple cubic centimeters per second may be achieved with this pumping apparatus, though pressures exceeding 200 millimeters mercury are considered unlikely since this would exceed intracranial pressures likely to be compatible with life. Infusate (i.e., infused liquid) temperatures varying between 32 and 110 degrees Fahrenheit may be achieved using this pumping apparatus.

monitoring physiologic and biochemical properties

The present devices that have passageways sized to slidably receive, and work with, at least a guidewire (including those illustrated as sheath **24** and catheter **42** in **FIG. 1**) may also have walls that have monitors therein. In this regard, **FIG. 14** illustrates a portion of device **90** having wall **92** and detector **94** attached to wall **92**. Detector **94**, although shown as attached to the exterior of wall **92**, may be embedded within wall **92** beneath the outer surface of wall **92** in certain embodiments, depending, for example, on the depth of detector **94** below the outer surface and the type of material from which wall **92** is made. In such an instance, device may be described as having wall **92** and a detector **94** "in" or "within" wall **92**, or "therein." Further, wall **92** may have an opening, and detector **94** may be attached to the inside surface of wall **92** and extending across that opening, provided proper precautions are taken to avoid damaging detector **94** as device **90** is navigated. Additionally, the location of detector **94** may be varied, from being at an end of device **90**, to being located at any position along wall **92**.

Detector **94** may be an electroencephalography electrode useful for monitoring electrical activity (i.e., an attribute). Detector **94** may be a sensor useful for monitoring a biochemical property (i.e., an attribute) such as pH, glucose concentration, oxygen

tension, carbon dioxide concentration, or sodium concentration. Thus, one of those biochemical properties may be monitored using the sensor. Detector **94** may be a thermal sensor useful for monitoring temperature (i.e., another attribute). Thus, temperature, such as of a fluid or a temperature, may be monitored using the thermal sensor. Detector **94** may also be useful for monitoring neurotransmitter concentration (i.e., an attribute). Thus, neurotransmitter concentration may be monitored using the detector. In this document (including the claims), an element such as a detector, which may take the form of a sensor, that is "useful for monitoring" something need only play a role in the monitoring, and need not completely perform all the steps necessary to achieve the monitoring. Also, in this document (including the claims), monitoring an attribute "using" a sensor or a detector means that the sensor or detectors is involved, or plays a role, in the monitoring, but need not be the only device used to achieve the monitoring

FIG. 15 is a cross sectional view of device **90**, showing that detector **94** may be coupled to a communication device that is illustrated as wire **96** embedded within wall **92**. It will be understood to those of skill in the art having the benefit of this disclosure that the communication device (in this case, wire **96**) may alternatively be secured to the outside surface of wall **92** as is detector **94**, or to the inside of the wall. The communication device may travel along the length of device **90** any sufficient distance, and may exit, or extend away from, wall **94** at any suitable location, including prior to the end of device **90** that is not shown in **FIG. 14**, at a hub coupled (whether permanently or otherwise) to the end of device **90** that is not shown, at the end of device **90** that is not shown, and at a valve apparatus (such as valve apparatus **36** illustrated, for example, in **FIG. 3**) coupled to the end of device **90** that is not shown. The communication device can then be linked to a station that processes the signal from the detector that travels along the communication device and that is useful in monitoring and controlling the detected attribute. The pumping apparatus disclosed herein may include that station. The station may be configured to record data that it collects and/or generates in monitoring and/or controlling the detected attribute on any suitable media, including paper and electronic data. The communication device can also take the form of a wireless communication using, for example, radio waves or other electromagnetic means of transmission.

FIG. 16 illustrates some of the benefits of the present methods. **FIG. 16** illustrates a patient positioned in MR scanner **100** and on top of sliding table **102**. Operator **104** is positioned remotely from the target area being scanned such that the magnets within MR scanner **100** do not interfere with his or her manipulations. Sheath **24** is shown as being inserted into the patient, and a communication device illustrated as wire **96** is shown traveling from outside of valve apparatus **36** to station **106**. Wire **96** is coupled to a detector (not shown) attached to the wall of the elongated member **24**. The hidden detector may be an electroencephalography electrode useful for monitoring electrical activity. The hidden detector may be a sensor useful for monitoring a biochemical property such as pH, glucose concentration, oxygen tension, carbon dioxide concentration, or sodium concentration. The hidden detector may be a thermal sensor useful for monitoring temperature. The hidden detector may also be useful for monitoring neurotransmitter concentration. Station **106** may be configured to record data that it collects and/or generates in monitoring and/or controlling the detected attribute on any suitable media, including paper and electronic data. Also, a second communication device in the form of wire **108** is illustrated as exiting station **106** and traveling to an undisclosed area where another operator can view the data generated and collected by station **106**.

The same types of monitoring that may be achieved using a detector attached to a device such as sheath **24** or catheter **42** (which is illustrated in the form of device **90** in **FIG. 14**), may also be achieved using a detector or detectors implanted in brain tissue or in the subarachnoid space. **FIG. 17** illustrates detector **112** that is positioned intracranially. **FIG. 17** shows brain **18** inside of head **110**, and further shows that catheter **42** may have a wall in which detector **94** is located. **FIG. 17** also illustrates that a communication device in the form of wire **96** is coupled to detector **94** and embedded within the wall of catheter **42**, as indicated by the dashed lines. A detector delivery mechanism illustrated as wire **114** is shown as being coupled to detector **112**. This coupling may be achieved through any suitable means, including electromagnetic means, and mechanical means such as clips, and temperature- or pressure-sensitive adhesives, and the like. Detector **112** may be coupled to wire **114** in a way that will allow the detector to be detached from wire **114** once detector **112** has reached its intended

destination. In such an embodiment, detector **112** may wirelessly communicate with a station like station **106** illustrated in **FIG. 16**. Alternatively, the detector delivery mechanism illustrated as wire **114** may remain coupled to detector **112** and serve as a communication device between detector **112** and a remote station. In any embodiment, detector **112** should be configured to slidably move within the passageway of catheter **42**. Devices, such as catheter **42**, may have passageways at least as large as 0.016" in the widest dimension and may be used to introduce detectors **112** to a desired location. Detector **112** may include an anchoring mechanism for retaining its position once delivered. This includes an anchoring mechanism that deploys once detector **112** exits catheter **42**; such an anchoring mechanism may have a non-tubular configuration. For example, one suitable anchoring mechanism that is also used in vascular systems involves "hooks" or "barbs" located at the tips of wire members of devices, which hooks engage the walls of vessels to hold the device in place. Such hooks may also be used as an anchoring mechanism to engage the dura in instances in which detector **112** is implanted in the subarachnoid space. Another suitable anchoring mechanism would be a flared end on detector **112**, resembling conventional flared configurations on the tips of conventional ventricular shunt catheters. Such an anchoring mechanism would be useful in instances in which a detector **112** is placed either in brain tissue or in a catheter destined for a ventricle. Like detector **94**, detector **112** may be an electroencephalography electrode useful for monitoring electrical activity. Detector **112** may also be a sensor useful for monitoring a biochemical property such as pH, glucose concentration, oxygen tension, carbon dioxide concentration, or sodium concentration. Detector **112** may be a thermal sensor useful for monitoring temperature. Detector **112** may also be useful for monitoring neurotransmitter concentration.

In addition to the embodiments illustrated in **FIGS. 14**, **15**, and **17**, multiple detectors **94** may be attached to the inside or outside surfaces of the wall of one of the present devices (such as sheath **24** or catheter **42**), or placed within the wall of one of the present devices, in order to better monitor the various attributes discussed above. Thus, 2, 3, 4, 5, 6, 7, 8, 9, 10, or more detectors may be placed on or in one of the present devices. Furthermore, a single communication device (such as wire **96**) may be used to link multiple detectors to a station. Additionally, each of the sub-elongated members

illustrated in **FIG. 13** may be provided with the detectors discussed above, in the manners discussed above. Thus, and by way of example, both of the sub-elongated members shown in **FIG. 13** may have walls that have detectors attached to them, and the lengths of those sub-elongated members may be such that the detector attached to one sub-elongated member may be placed in brain tissue and may be useful for monitoring oxygen tension, while the detector attached to the other sub-elongated member may be placed in cerebrospinal fluid and may be useful for monitoring sodium concentration.

placement of electroencephalography electrodes

As discussed above, detectors that are electroencephalography (EEG) electrodes may be introduced into the subarachnoid space in both the spinal and intracranial regions, and in brain tissue using the present methods. By way of explanation, in epilepsy treatment, it is often difficult to localize the site of a seizure focus. One technique used in particularly difficult cases involves placement of EEG electrodes either directly on the surface of the brain (electrocorticography) or within the brain substance (depth electrode implantation). Since EEG monitoring involves detection of extremely weak electrical signals that are emitted from brain cells, elimination of interference from scalp muscles, elimination of signal resistance from the skull bone, and placement of electrodes closer to the brain tissue emitting those signals is one way to increase the sensitivity and specificity of localization and detection.

While increasing the sensitivity and specificity of epileptiform activity detection, such techniques as electrocorticography and depth electrode implantation have traditionally been invasive, requiring either burr holes in the skull for depth electrode placement or craniotomy for cortical array placement in electrocorticography. If bilateral monitoring is desired, bilateral burr holes or craniotomies have been necessary.

However, using the present methods, which involve percutaneous access to the subarachnoid space, usually in the lumbar region, followed by placement of devices such as sheath **24** and catheter **42**, EEG electrode placement may be achieved, for example, in the cerebral subarachnoid space after entry via the foramen magnum. EEG electrodes may be placed on the surface of the brain or within brain tissue using the present methods.

In instances in which EEG electrodes take the form of detectors **112** discussed above with respect to **FIG. 17**, multiple detectors may be linked with a single communication device (also discussed above) that takes the form of a wire. Multiple wire and detector(s) combinations may be placed during a single procedure, and the different wires may have different diameters, different stiffnesses, or the like. Thus, arrays of EEG electrodes may be placed on or within brain tissue to map out the electroencephalogram from the deep brain structures. As an exemplary description of the manner of placing multiple EEG electrodes, a catheter having two passageways may be advanced to a desired location over a guidewire positioned in one of the two passageways. An EEG electrode may then be placed in a desired location through the open passageway. After placement, the catheter may be withdrawn over the guidewire, leaving the guidewire and the first EEG electrode in place. The catheter may then be reintroduced over the guidewire, and a second electrode placed in a desired location through the once-again open second passageway. This process may be repeated as many times as necessary.

In instances in which the EEG electrodes take the form of detectors **94** discussed above with respect to, for example, **FIG. 14**, multiple detectors may be linked with a single communication device (as discussed above) that takes the form of a wire, and multiple wire and detector(s) combinations may be attached to a device such as sheath **24** or catheter **42**. Furthermore, one or more wire and detector(s) combinations can be attached to guidewires such as guidewire **44** shown in **FIG. 1**.

spinal and cerebral stimulation

There are situations in medicine and in research where it is desirable to deliver an electrical impulse to the brain and spinal cord. Using the present methods, an electrode suited to such stimulation may be placed, thereby enabling the application of electric current, heat, or cryothermal stimulation of a patient's tissue. Such electrodes may be configured the same way at detectors **94** and **112** discussed above – that is, they may be attached to, or placed within, the wall of a device such as sheath **24** or catheter **42**, or they may not be associated with a device, such as can be achieved using detector **112**. Furthermore, a transmission device such as a wire may be coupled to the electrode (and

either attached to a device like sheath **24** or catheter **42**, or not attached in that fashion, depending on the application) to introduce the stimulating signal to the electrode. However, the stimulating signal may also be introduced to the electrode via a wireless transmission. Furthermore, in certain embodiments in which a transmission device such as a wire is used, the wire may be linked to a station useful in delivering the stimulating signal, and that is located outside of the patient's body or implanted within the patient, such as a station that is implanted in the subcutaneous space of the patient. Such stations currently exist in cardiac pacemakers and in transcutaneous neural stimulation devices used for pain control.

implantation of radioactive pellets, or beads, for treatment of tumors

The present methods can be used to implant radioactive pellets, or bead, into patients, in areas such as the brain, in order to irradiate a tumor. While the use of radioactive pellets for tumor irradiation is known, the placement of such pellets using the present methods is novel. As with all the other applications that may be achieved using the present methods, the placement of radioactive pellets may be monitored under direct MR visualization. Further, a series of pellets may be implanted into patients using a smaller introduction apparatus than is currently utilized for placing the pellets using conventional techniques.

ablation of brain lesions

In functional neurosurgery, it is sometimes desirable to create lesions in the brain. This is seen in chronic pain syndromes, Parkinson's disease, and other settings. Current techniques for creation of these lesions involve CT- or MR-guided stereotaxis, in which a cryothermal or thermal ablation device is introduced to the desired location in the brain via a burr hole in the skull that the neurosurgeon drills in the operating room.

Using the present methods, a device (such as sheath **24** or catheter **42**) or a guidewire (such as guidewire **44**) may be introduced into the subarachnoid space (for example, the spinal subarachnoid space) and advanced as described above with respect to **FIG. 1** to a desired location. Energy, such as thermal energy or cryothermal energy, may then be applied either to an ablation device imbedded in or attached to the catheter, sheath, or guidewire or to an ablation device introduced through the passageway of the

catheter or sheath such that a lesion is created in the adjacent tissue, such as brain tissue. Other areas of application include tumors that may be in locations that are either inaccessible via conventional techniques, or that require unacceptable morbidity to approach them via conventional techniques. Such locations may include locations in the brain stem, the spinal cord, or in the subarachnoid space. In cases in which the ablation device is attached to or embedded within a device or a guidewire, the ablation device may be positioned at the end of the device or guidewire, or it may be positioned at any suitable location along the length of the device or guidewire.

By using one or more imaging modalities to monitor the therapy resulting from the ablation may make it feasible to create a lesion, observe partial success, and enlarge the lesion without repositioning the introducing device (such as catheter **42**), or with minimal manipulation of the introducing device. Furthermore, tissue ablation achieved using the present methods may be performed in conjunction with conventional surgery such that lesions are created either before or after conventional resections, either to enhance the resection preoperatively or to improve margins of incompletely-resected lesions, or to provide an alternate approach to large-scale resections in diseases with multiple brain lesions such as metastatic disease from different forms of malignancy.

accessing one or more ventricles

In medicine, the ventricular system is frequently catheterized, both temporarily (ventriculostomy) and permanently (shunting). This occurs to combat hydrocephalus, to monitor pressure and, less often, for introduction of various medications or withdrawal of cerebrospinal fluid. However, the current neurosurgical approach requires placement of a burr hole in the skull bone and insertion of the catheter through the brain tissue – usually the frontal or parietal lobe – to access the ventricles.

Using the present methods of percutaneous subarachnoid navigation, the lateral ventricles, the 3rd ventricle, and the 4th ventricle may be accessed via medical devices such as catheter **42** or guidewire **44**. Accordingly, using the present methods, at least one ventricle located within the head may be accessed. Imaging modalities may be used as described above (and with all the movements of medical devices described herein) to monitor the position of such devices as they approach and enter a ventricle.

Furthermore, using the present methods, at least one ventricle located within the head may be drained. For example, in applications involving shunting, there will be a need for placement of a shunt component in the peritoneal cavity or venous return to the heart. This may be accomplished using the present methods. Specifically, after percutaneously introducing a device (such as sheath **24** or catheter **42**) into the spinal subarachnoid space at an entry location, the device having a first passageway sized to slidably receive, and operate with, at least a guidewire, and advancing the device within the subarachnoid space at least more than 10 centimeters from the entry location, or to facilitate intracranial access with a second device introduced through the first passageway, one or more ventricles located within the head may be accessed and/or drained. The draining may be achieved using a commercially available mechanism that spans a ventricle and a drainage location, and that acts as a one-way valve that allows that CSF and other fluid to flow in one direction – away from the ventricle or ventricles in question.

brain biopsies

The brain is a very soft and gelatinous tissue once the membrane surrounding it (pia) is penetrated. Neurosurgeons resecting brain often use a tubular apparatus attached to suction to aspirate brain tissue rather than cutting it with a scalpel or scissors. That quality of brain tissue should lend it to biopsy by way of aspiration.

Using the present methods, a device may be introduced through the passageway of a device such as catheter **42** or sheath **24** that may be used to remove a part of the brain. For example, the device that may be used to remove a part of the brain may be a traditional stereotactic device that is configured for introduction through the passageway of a device such as catheter **42** or sheath **24**.

Alternatively, a device such as catheter **42** or sheath **24** may be coupled to suction by was of a syringe or other mechanism, and used to retrieve a sample of tissue located at the tip of the catheter or sheath. Another feature of biopsies is that often multiple samplings of tissue are required to retrieve diagnostic material. Hence, it may be necessary to reposition the catheter or sheath for more than one biopsy sample. Once the device has been positioned the first time, it is desirable to avoid having to repeat the

navigation that was performed to achieve initial positioning. Thus, using an embodiment of the sheath or catheter that has two passageways, an operator may be able to use the sheath or catheter in the manner discussed above with respect to EEG electrode placement. That is, the sheath or catheter may be positioned proximate (i.e., near) a target area, suction may be applied to an open passageway to retrieve a portion of the brain. The sheath or catheter may then be removed along the guidewire used to initially facilitate placement (leaving the guidewire in position), and if the tissue sample is inadequate, the catheter or sheath can be repositioned over the guidewire and another biopsy sample can be obtained in a similar manner. Without the retention of the guidewire via the one of the two passageways, it would be necessary to reposition from scratch, repeating whatever risk or difficulties were encountered during the first catheter or sheath placement.

treating neurologic conditions

Using the present methods, genetic material may be introduced through the passageway of a device such as catheter **42** or sheath **24** and placed within a patient suffering from a neurologic condition in order to assist in treating that neurologic condition. Such genetic material may include human stem cells.

Furthermore, neurologic conditions arising from pressure on cranial nerves may also be treated using the present methods. For example, the present methods may be used to perform microvascular decompressions. In such an application, a device (such as sheath **24** or catheter **42**) may be percutaneously introduced into the spinal subarachnoid space at an entry location, the device having a first passageway sized to slidably receive, and operate with, at least a guidewire; the device may be advanced within the subarachnoid space at least more than 10 centimeters from the entry location, or to facilitate intracranial access with a second device introduced through the first passageway; and a second device (which may be described as "material") may be introduced through the first passageway and placed between a vascular loop and one or more cranial nerves (which may take the form of placing the device proximate a cranial nerve) in order to relieve compression of the cranial nerve by the vascular loop.

Furthermore, a second device may be introduced through the first passageway and used to cut a nerve, such as a cranial nerve.

vascular coagulation or cauterization

Using the present methods, vessels may be coagulated at the time of surgery, either because they are observed to bleed or in order to prevent bleeding. Specifically, a device (such as sheath **24** or catheter **42**) may be percutaneously introduced into the spinal subarachnoid space at an entry location, the device having a first passageway sized to slidably receive, and operate with, at least a guidewire; the device may be advanced within the subarachnoid space at least more than 10 centimeters from the entry location, or to facilitate intracranial access with a second device introduced through the first passageway; and an apparatus that is or that is like a "two-point" or "Bovie" apparatus (which are used in conventional surgery or neurosurgery) configured for introduction through the first passageway may be introduced through the first passageway and used to coagulate a vessel.

In conventional surgery, a metallic electrode is applied to a bleeding vessel and a current is applied through the electrode that heats the tissue such that the vessel is cauterized. That cauterization is achieved with the "two-point" apparatus via approximation of the points of a forceps, thus completing the current loop. However, monopolar cautery apparatuses also exist, and may be configured for introduction through the first passageway of a device introduced as described above.

Thus an apparatus having a cauterization element and a transmission device (such as a wire, an insulated wire, a wire loop, or an insulated wire loop) connected to the cauterization element that is configured for attachment to a current-inducing apparatus may be used with the present methods to apply heat to a vessel, thereby cauterizing or coagulating it. Alternatively, the apparatus may include a set of forceps positioned at the end of a guidewire as the cauterization element, which forceps would function to open and close and act similarly to the forceps on conventional "two-point" devices. The apparatus should be configured for introduction through the first passageway (as discussed above), or it should be combined with one of the present devices, such as catheter **42** or sheath **24**, in the manner that detector **94** discussed above may be attached

to device **90**. The transmission device may be attached to one of the present devices (including a guidewire) in the same manner discussed above with respect to wire **96**. The transmission device that is part of this apparatus may be a wire loop that flares slightly after it exits the passageway through which it is introduced.

Hence, using the present methods, a device (such as sheath **24** or catheter **42**) may be percutaneously introduced into the spinal subarachnoid space at an entry location, the device having a first passageway sized to slidably receive, and operate with, at least a guidewire; the device may be advanced within the subarachnoid space at least more than 10 centimeters from the entry location, or to facilitate intracranial access with a second device introduced through the first passageway; and an the aforementioned apparatus configured for introduction through the first passageway may be introduced through the first passageway, current may be introduced to the cauterization element, the cauterization element applied to a selected vessel tissue, and coagulation achieved.

Cadaver studies

materials and methods

Two recently deceased, unembalmed male human cadavers were placed in prone positions. Using fluoroscopic guidance, lumbar punctures were performed in each subject at both the L3-4 and L4-5 interspaces using a standard, single-wall puncture angiography needle. A 0.038 inch guidewire was then introduced and directed superiorly. Subsequently, a 5 French (F) angiographic dilator was advanced into the subarachnoid space over the guidewire to dilate the tract, and a 5F arterial sheath was placed with its tip directed superiorly. In each cadaver, one sheath was subsequently used for catheterization posterior to the spinal cord and the other was used for catheterization anterior to the spinal cord.

Following sheath placement, angiographic techniques were applied to the subarachnoid space. Specifically, under fluoroscopic guidance a hydrophilic-coated angle-tipped guidewire (Radifocus Glidewire, Terumo, Inc., Tokyo, Japan, distributed by Meditech Boston Scientific Corp., Watertown, MA) was advanced with its tip directed either anteriorly or posteriorly under operator control. Care was taken to maintain a midline position whenever possible, but it could not always be maintained.

The advancement was performed with inflation of the subarachnoid space via saline infusion. The pressure of the infusion was easily controlled via management of the height of the flush bag above the patient's spine, though the pressures of the infusion and of the subarachnoid space were not specifically monitored.

After entering the cranial space, manipulations with the catheters were undertaken to explore areas for catheterization. Following catheterization manipulations, the catheters were left in place for subsequent dissection. The sheaths were cut at the skin with the introducers and microcatheters in place using standard wire cutters. The stumps of the systems were then oversewn and the cadavers were embalmed.

Following embalming, one cadaver was examined for evidence of spinal cord injury from the catheterization process. Laminectomy was performed throughout the cervical and thoracic spine and extended inferiorly to the point of catheter entry. The opened dura was photographed with the catheters in place. The spinal cord was removed and photographed with the ventral catheter in place. Brain dissections were performed to confirm catheter locations and to examine for unanticipated injury to brain tissue, with specific attention to the optic chiasm region in the case of catheters which passed through that region.

results

In each case, the guidewire advanced relatively easily through the thoracic and cervical spine. In some cases, the catheter was advanced readily without guidewire placement. Once at the foramen magnum, attempts were made with the posterior catheters to enter the 4^{th} ventricle. Observation was made during these attempts that navigation of the retrocerebellar space in the posterior fossa occurred relatively easily, on some occasions circum-navigating the posterior fossa to a position anterior to the pons. Also, advancement superiorly behind the cerebellum to the level of the tentorium occurred relatively easily. In each cadaver, a tough membrane was encountered at the base of the skull when midline catheterization was attempted. Whereas deflection of the guidewire for lateral or posterior catheterization occurred easily, the soft tip of the guidewire was inadequate for penetration of the membrane in the midline and the stiff end of the guidewire was used to penetrate the membrane. Subsequently, catheterization

superiorly proceeded easily. In Cadaver 1, the posterior fossa catheter ultimately traversed the cerebellum during an attempt at fluoroscopically-directed 4th ventricular catheterization. In Cadaver 2, the 4th ventricle was successfully catheterized and injected with contrast, as described below.

Attempts were made without complete success to determine the location of the 4th ventricle using only fluoroscopy. Contrast injections resulted in intracranial spilling of contrast without outline of cerebellar structures. Blind passes with the catheter to where the 4th ventricle should be resulted in successful catheterization of the 4th ventricle in one of the two subjects. This was confirmed with contrast injection showing filling of the 4th ventricle, retrograde flow into the aqueduct of Sylvius, flow into the 3rd ventricle, and subsequent flow into the frontal horns of the lateral ventricles bilaterally via the foramina of Munro.

In both subjects, catheterization of the subarachnoid space anterior to the pons occurred easily. Catheters as large as 5F were successfully advanced to this position. At the upper pontine level, a tough membrane was encountered in both subjects that would not permit higher catheterization using standard techniques. In both cases, the guidewire was deflected repeatedly from that location, regardless of multiple catheter repositioning attempts. Therefore, the guidewire was reversed and the stiff end of the guidewire was used to "punch" through this membrane. The membrane was believed to be the membrane of Lilequist, though this could not be confirmed with certainty subsequent to the dissection. Once it was crossed, catheterization to the suprasellar cistern with the standard end of the microguidewire (Radifocus™ Guide Wire M, Terumo, Inc., Tokyo, Japan, Tapered Glidewire Gold™ .018-.013 inches, distributed by Target Therapeutics Boston Scientific Corp., Fremont, CA) proceeded smoothly. A Transit® 18 microcatheter (Cordis® Endovascular Systems, Johnson & Johnson, Miami Lakes, FL) was used in most cases, using in some cases a Tracker™ 38 catheter (Target Therapeutics® Boston Scientific Corp., Fremont, CA) as a guide catheter. In Cadaver 1, a single 4F introducer catheter was used that came from a company bought by Medtronics (MIS, Inc., Sunnyvale, CA) that is now no longer commercially available. With that catheter, the introducer catheter was advanced to the suprasellar cistern.

Once in the suprasellar cistern in Cadaver 1, advancement of the catheter was relatively easy, and catheterization of the sylvian fissure was observed and confirmed when contrast was injected and seen to flow dependently within the fissure. The catheter was left in that position and the subject was embalmed.

In Cadaver 2, catheterization of the suprasellar cistern was followed by experimentation regarding the degree of control had over placement. First, the frontal fossa on the side opposite from the previously catheterized middle fossa was catheterized. The catheter was advanced along the orbital roof and observed to curve superiorly, with its tip ultimately anterior to the frontal lobe and deep to the frontal sinus. The catheter was then withdrawn to the location on the orbital roof and this was confirmed with contrast injection. Next, that catheter was repositioned and the contralateral floor of the middle cranial fossa was catheterized and confirmed with contrast injection.

The posterior fossa catheter was then advanced and seen to be in the 4th ventricle, as described above. After contrast injection, some opacification of the 3rd ventricle was seen. This opacification was used as a "road map" for the anteriorly placed catheter and attempts were made to catheterize the 3rd ventricle directly through the region of the interpeduncular cistern (with fluoroscopy, the exact position was not identified). The pial lining of the undersurface of the brain resisted perforation with the soft end of the guidewire and the ventricle was elevated by the attempt but not punctured. Ultimately, however, the 3rd ventricle was entered successfully, as evidenced by drainage of the retained contrast. This was subsequently confirmed directly by contrast injection through the 3rd ventricular catheter. This subject was then embalmed.

Cadaver 1 was the only subject in which the spinal component of the catheterization was examined anatomically. Following full spinal laminectomy from the upper cervical area to the area of puncture in the lumbar spine, the posterior dura was incised and reflected. The dorsal introducer catheter was seen lying superficial to the spinal cord without apparent spinal cord violation or laceration. This was then removed and the spinal cord was resected by cutting the nerve roots bilaterally and lifting it out, retaining the ventral catheter with the spinal cord. It was observed to traverse

anterolaterally, weaving anterior and posterior to different nerve roots. Again, there was no apparent spinal cord violation or laceration.

In Cadaver 1, anatomic exposure of the brain was preceded by latex impregnation of the vasculature following decapitation, with arteries impregnated with red latex and veins impregnated with blue latex. Dissection was performed via extensive bone drilling of the left frontotemporal area to reproduce an expanded surgical approach to the sylvian fissure and the region of the basilar apex. Exposure using an operating microscope revealed the microcather anterior to the midbrain, between the clivus and midbrain. It was followed inferiorly as it migrated to the right side of the basis pontis. There was no apparent violation of cerebral structures by the catheter during its passage anterior to the brain stem. The catheter traversed laterally in a sulcus in the left sylvian fissure. Removal of the temporal lobe revealed the catheter in the sylvian fissure, near branches of the middle cerebral artery. The posterior fossa catheter was observed to enter the cerebellum and was not pursued via further detailed dissection.

Dissection of Cadaver 2 revealed the 3rd ventricular catheter to be in place as suspected from the radiographs, located within the 3rd ventricle. The catheter was seen passing anterior to the brain stem along the clivus without brain stem penetration. Also, the basilar artery was seen separate from the catheter. The point of penetration of the 3rd ventricle was essentially vertical in the midline from the interpeduncular cistern. The 4th ventricular catheter was under some tension and sprang laterally as the cerebellum was split in the midline and its exact location could not be reconstructed. However, based on the images during contrast injection, it appeared to lie in the cerebellar tissue in the roof of the 4th ventricle.

All of the present methods and devices disclosed and claimed herein can be made and executed without undue experimentation in light of the present disclosure. While the this invention has been described in terms of specific embodiments, the described embodiments are not exhaustive, and it will be apparent to those of skill in the art that other variations exist. For example, the flexible member portion that extends away from a skin-attachment apparatus (and thus away from a patient) should enhance robotic applications in angiography similarly to their enhancement of robotic access of the

subarachnoid space. Also, the flexible member portion enables angiographic applications in which the sheath is placed in a femoral artery and the patient is rolled into a supine position for intraspinal or other surgical access posteriorly while retaining anterior arterial access for angiography via the flexible member portion, which can be placed out from under the patient.

REFERENCES

The following references, to the extent that they provide exemplary procedural or other details supplementary to those set forth herein, are specifically incorporated herein by reference.

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